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14. ABSTRACT

The purpose of this project is to help prevent psychological disorders in high-risk individuals with early symptoms of stress, depression, substance use, and other health problems. Military medicine is increasingly concerned with the incidence of psychological casualties and the treatment of post-traumatic stress disorder (PTSD) in returning personnel. This incidence increases the need for medical care and reduces operational readiness. Few preventive methods are available to mitigate subclinical psychological health issues upon the return of personnel from deployment. The PHIT for Duty system is a personal health intervention tool (PHIT) using mobile smartphone technology to integrate personal health assessment with targeted self-help intervention for the mitigation of psychological symptoms, modification of risky behaviors, and provision of cognitive support. The study will identify self-help interventions to assist individuals in dealing with combat and operational stress; develop smartphone applications for health assessment and self-help intervention; and evaluate the PHIT methodology for prevention of psychological disorders in post-deployed personnel. Improvements in patient-related outcomes are expected to be demonstrated in 2-3 years. The PHIT for Duty mobile health approach can be transitioned for chronic disease management, obesity prevention, substance use intervention, and other domains where better personal health management could improve wellness and clinical outcomes.

15. SUBJECT TERMS
PTSD, post-traumatic stress disorder, mobile health, smartphone, self help, iPAD, Android

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1. INTRODUCTION

The goal of this project is to support prevention of psychological health problems and post-traumatic stress disorder (PTSD) through innovation in mobile personal health assessment and self-help intervention (SHI).

Our objective is to develop and evaluate PHIT for Duty, a field-deployable personal device to help build resilience in healthy troops and support prevention in high-risk personnel. Based on RTI's Personal Health Intervention Tool (PHIT) platform, PHIT for Duty will integrate a suite of health assessments with an intelligent virtual advisor (iVA) that recommends, tailors, and presents self-help advisories based on established rules and processes. The PHIT platform will comprise a smartphone or tablet and optional, nonintrusive physiological and behavioral sensors for health status monitoring and intervention.

PHIT for Duty is intended to be used for secondary prevention of psychological health problems in persons who have been exposed to psychological trauma and may be having some symptoms of distress, but have not been diagnosed with any psychological disease or disorder. PHIT for Duty, however, may eventually prove useful as a treatment option, and therefore should be developed according to good software development practices.

The project comprises (1) formative research to identify psychological assessments and SHIs to assist individuals in dealing with combat and operational stress and the psychological and physiological consequences of that exposure; (2) development of personal, mobile technologies for longitudinal health assessment and SHI; (3) testing, refinement, and validation of PHIT for Duty technologies through beta testing and pilot studies; (4) evaluation the efficacy of the PHIT methodology for prevention in a randomized controlled trial (RCT) with post-deployed personnel; and (5) adapting the developed system for several popular smartphone or tablet computer platforms, including both Google Android™ and Apple iOS based devices.

2. BODY

2.1. Task 1: Concept formation and development planning

The goal of this task is to establish the vision, requirements, and approach for PHIT for Duty development and evaluation through a series of interactions with scientific and clinical advisors, military leaders, prospective users, and other stakeholders. Our objective is to identify preventable psychological health problems that might be mitigated using PHIT for Duty, potential self-help interventions to incorporate in the device, operational issues regarding PHIT for Duty use post deployment, and the applicability and potential concerns for PHIT for Duty during deployment. More specifically the aim was

to identify the needs of PHIT end users and stakeholders and develop user-centric design concepts and specifications. Formative research was necessary to identify and understand the preventable psychological health problems, potential SHIs, operational requirements, and deployment concerns.

2.1.1. Focus Groups

Three focus groups were conducted during the summer of 2012 with soldiers from the Warrior Transition Battalion (WTB) at Ft. Bragg. Each session lasted approximately 90 minutes. The project team worked with a designated point of contact (POC) from the WTB to arrange the focus group sessions. The POC identified participants, explained the voluntary nature of their participation, and scheduled the focus groups. Focus groups were conducted in a private conference room housed at the WTB headquarters. A trained focus group moderator led each discussion using the RTI and WMAC IBR approved focus group moderator's guide. A note taker was also present in the room. Informed consent was obtained at the start of each focus group session. Each session was audio recorded.

There were a total of fourteen participants across three groups. All of the focus group participants were male. All participants had at least one combat deployment. The number of deployments ranged from one to six, with the average number of deployments being two. All participants had returned from deployment within the last twelve months. One participant had returned from deployment six weeks prior to the focus group session. During the focus group, the RTI team took measures to ensure that the soldiers felt emotionally and physically comfortable sharing their experiences. More specifically, participants were allowed to sit wherever they chose in the room. One participant shared that he needed to sit in "his safe space" which was across from the door and with his back to the wall. He also requested that the group not make eye contact with him as it would make him feel uncomfortable and he might "flip out." The moderator was sensitive to the vulnerability of these participants and would redirect conversations that were becoming emotionally charged.

The questions asked during each session focused on key areas that would help the research team identify psychological health problems, SHIs, operational issues, and deployment concerns. Additional topics discussed include post-deployment health problems, incentives for participation in the study, study recruitment strategies, device usage preference (tablet vs. smartphone), acceptability of proposed SHIs such as relaxation exercises, and willingness to use physiological monitoring devices.

2.1.2. Findings

Post deployment health problems. The top three post deployment health problems mentioned were depression, anxiety and sleep issues. Additional post deployment health problems discussed include stress, aggression, social withdrawal/avoidance, memory issues, substance abuse, nightmares, breathing problems, and pain. The specific types of stress mentioned include financial and relationship stress experienced after returning from deployment. Participants across all three groups discussed the stigma associated with seeking help for most post deployment health problems mentioned. It is also important to

note that soldiers reported that many post deployment health problems do not appear until a few months after return from deployment.

- "I can't stay asleep and sleep about an hour and then wake up and stay up for maybe two or three hours. This happens night after night."
- "Crowds and traffic are difficult. You are constantly on guard about people coming close to you and vehicles driving near you."
- "Nothing really happens the first three months (post deployment) when you are trying to unwind and get back into your life."

Post deployment support. Participants acknowledged the stigma associated with seeking help for most of the post deployment health problems cited above. Across all three focus groups, soldiers reported not being honest when responding to post deployment health assessments. Soldiers responded positively about the provision of post deployment support by way of an app on an electronic device. The use of this app would allow for soldiers to seek help privately without calling attention to their difficulties adjusting post deployment thus reducing the stigma and risk associated with utilizing behavioral health services. Participants recommended that the study emphasize that the names of soldiers who use the app after deployment will not be shared with the chain of command. The importance of confidentiality was repeatedly mentioned.

- "The Army offers a lot of resources (for post deployment issues) but what happens, I think, is that if a solider decides to use it he worries too much about the consequences of what people are going to think and it is like taboo and that is what it comes down to."
- "If you are labeled a soldier with PTSD then you automatically trigger thoughts of them being crazy."

Incentives. Numerous incentives were discussed during the focus groups. Soldiers reacted positively to the idea of being provided with a portable electronic device for three months. The provision and use of an electronic device would serve as an incentive for many soldiers to help encourage participation in the study if the device could be used for their personal use. Soldiers clarified that their strong preference would be for the provision of a tablet as opposed to a smartphone, as most soldiers already own a smartphone. All soldiers agreed that access to free Wi-Fi, movies, music, and games would be an incentive. The use of new and/or hard to obtain electronic devices would be an additional incentive.

- "Games like Angry Birds would be good."
- "The appeal would be the model (of electronic device) and if it were hot off the press kind of thing."

Study recruitment. A major theme that was present in all focus group discussions regarding study recruitment was the importance of stressing confidentiality and the voluntary nature of the study. Soldiers did not want their chain of command to be notified of their study participation and strongly suggested that recruitment efforts not be associated with the Army. Soldiers shared that the study team

would need to gain the trust of the soldiers. More specifically, trust that we would not share their data with their chain of command was emphasized. Once trust was established, soldiers would suggest the study to their peers which would aid in recruitment efforts. One participant thought that younger soldiers would be harder to recruit because they think they are "indestructible." Another suggested recruitment strategy was to hold "briefing" sessions off base (again stressing the separation of the study and the Army). Recruiting via Facebook or radio commercials was also suggested. Contrary to what was previously shared, one soldier recommended that we partner with Military Family Life Consultants (MFLC). MFLC are not allowed to inform the chain of command unless a soldier is threatening to hurt themself or others. Barriers to participation included the time commitment and soldiers not wanting to address post-deployment problems for fear of being identified by their chain of command. In conclusion, recruitment efforts will need to stress confidentiality and, if possible, not involve the chain of command.

- "The Military Family Life Consultants (MFLC) would be good and can't tell your chain of command and are under the radar."
- "Keep everything confidential about what is being put in that system. Keep stressing confidentiality because of the trust issue with soldiers."

Use of physiological monitoring devices. The majority of focus group members were enthusiastic and amenable to using the psychological monitoring devices (ear clip to monitor heart rate, and Zeo headband to monitor sleep). Concerns were mentioned about charging the devices. There was significant interest in monitoring sleep behaviors as many soldiers shared having sleep issues post-deployment. Soldiers were eager to receive feedback on their quality of sleep. One participant suggested the use of a sleep monitor would encourage participation and this could be focused on during recruitment. Feedback from the physiological monitoring devices may serve as an incentive for some participants.

- "I would be willing to that (wear sleep monitor). I would really like to know how I am sleeping."
- "I personally think it would be fun to see what my heart rate was doing."

General feedback. Soldiers suggested sending study reminder notifications via text message to their personal phone to ensure compliance with the daily health assessments. The length of the SHIs should be ten minutes or less per day. Soldiers would lose interest after ten minutes. We received mixed feedback on the relaxation exercises. A few participants have practiced relaxation techniques and have found them effective. Soldiers consistently shared that they are interested in receiving feedback on how their health has changed over time. One soldier feels that participants will just tell us "what we want to hear." The use of the app by family members was suggested numerous times. Soldiers feel that the family/friends could benefit from learning more about how to cope with post-deployment health issues. Soldiers recommended that the app include an easy to find resource list on phone numbers if needed.

- "The app is clean and I like it a lot".

- ”If you stress that you are building a system to help future soldiers and not say that we are analyzing them (the participant) they won’t feel like they are being judged and are more likely to help (participate).”

2.1.3. Conclusions

After reviewing these finding and discussing our observations, we arrived at the following overall conclusions:

- If possible, PHIT for Duty should be implemented three to six months post-deployment, as this is the timeframe when post-deployment health issues surface.
- The mobile electronic device of preference was the tablet.
- Study recruitment efforts will need to stress confidentiality and if possible not involve the chain of command.
- Soldiers have concerns about confidentiality.
- Soldiers are willing to use the physiological monitoring devices. Feedback provided by these devices could serve as an incentive.

2.2. Task 2: Prototype design and development

2.2.1. Overall system architecture

One of our goals is to create a common mobile health platform from which many other mobile health management and data gathering applications can be readily developed, and to experiment with alternative ways of configuring the data input instruments. The PHIT system accomplishes this, in part, by integrating different forms of data inputs ranging from survey style questionnaires to diaries to external physiological and environmental sensors.

The PHIT platform is a mobile application framework that integrates multimodal data collection with an intelligent virtual advisor that analyzes real-time data to recommend, tailor, and present domain-specific activities based on established rules and scripted processes (**Exhibit 1**). PHIT facilitates building complex smartphone/ tablet applications with both self-entry and autonomous sensor-based instruments. Objective data are acquired via cognitive tests, interactive exercises, serious games, and various Bluetooth sensors. Periodic assessments of various domains are analyzed to instruct users and recommend activities tailored to the scope of the application. All acquired data are stored on the mobile device using an encrypted database, periodically uploaded to a secure server, and made available for quality review and analysis via a password-protected website.

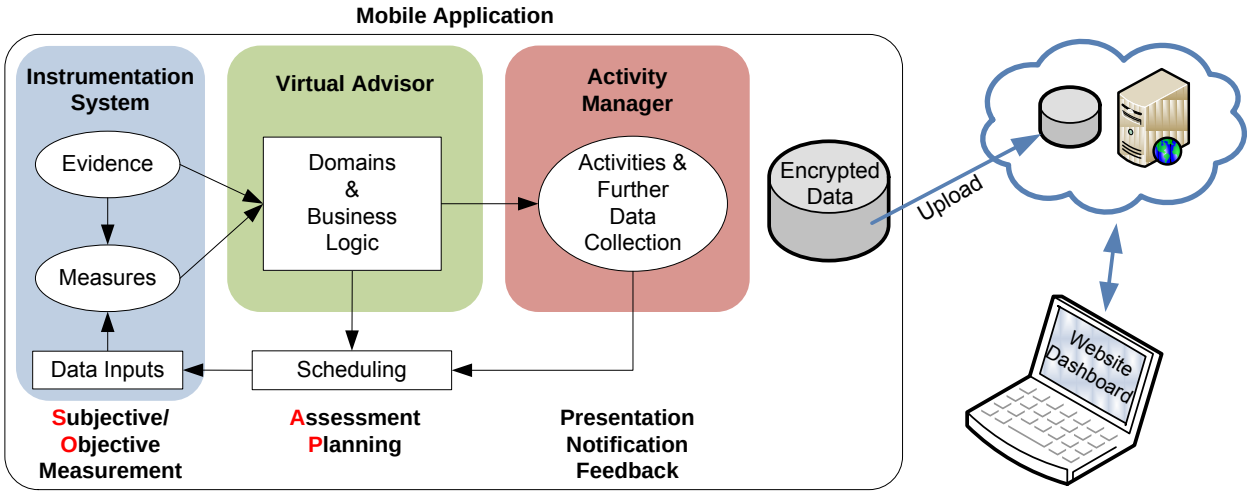


Exhibit 1. PHIT mobile application framework architecture.

The generic PHIT platform is highly extensible, flexible and secure. Developing PHIT components such as instruments, activities, and intelligent Virtual Advisor (iVA) modules is straightforward yet the XML structures provide considerable power in customizing the content. For example, sub-scores and the overall score for a user for a questionnaire (e.g., for anxiety) are immediately available to the iVA, which is able to determine how to proceed with the user. The iVA may choose to schedule a screening for a future date, to place a SHI on the user's task list, or, if necessary, contact a clinician for referral. Variations of instruments, new instruments that focus group participants suggest, and advisory content that improves the PHIT device's usability are easily accommodated.

Additionally, we have worked with clinical experts to implement a range of domains and instruments that are evidence-based, and thus justifiable. For example, the primary domains are those that clinicians feel are most important to individuals with post traumatic stress, and the iVA's underlying algorithms are written to carefully consider variation in assessments of these domains. Other data (e.g., resilience, combat exposure, and family history) are captured through additional validated and custom instruments that will be used as covariates in analyses to better explain trends found in the main domains.\

The PHIT for Duty application comprises a variety of subjective and objective data collection instruments, interactive self-help activities, health information, personal feedback, and other presentation modules (**Exhibit 2**). Required user actions, like completing a brief morning sleep quality questionnaire, are managed via a task menu screen. The task list is updated each day according to logic rules managed via the intelligent virtual advisor.

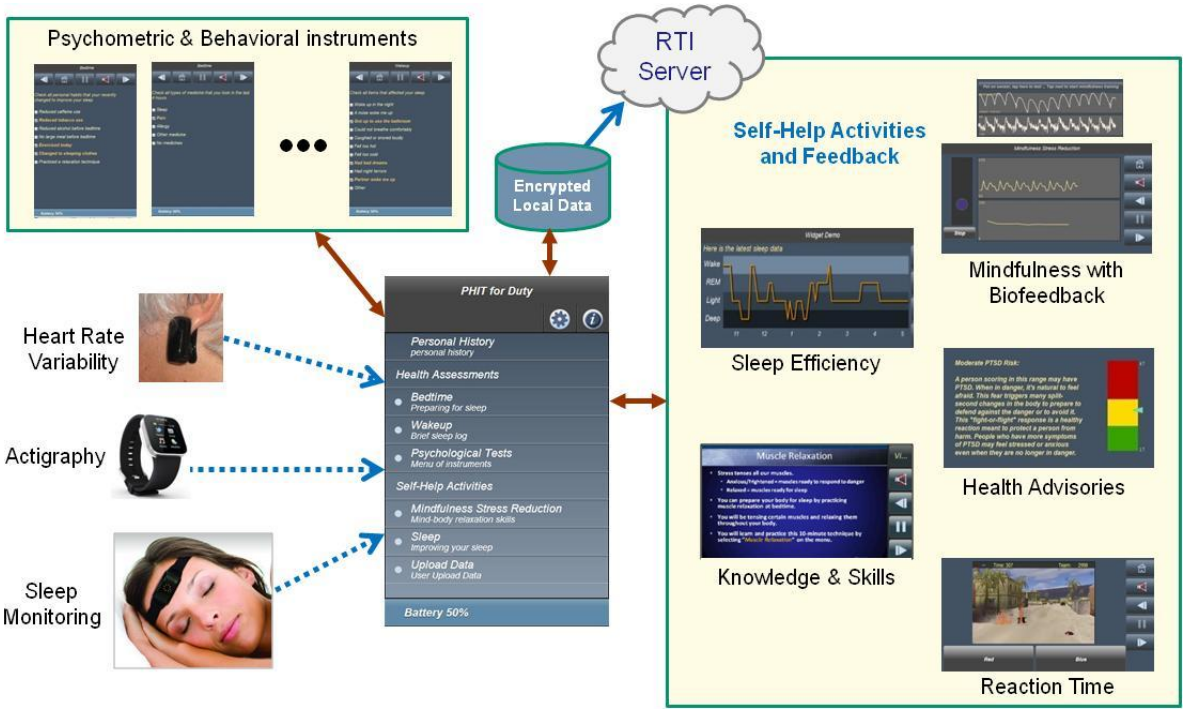


Exhibit 2. Representative data collection instruments, user task menu, self-help activities, and health information feedback modules in the PHIT for Duty application.

A summary of the planned health assessment and preventive intervention schema is presented below (**Exhibit 3**). At baseline, personal, psychological, social, and combat history data will be collected via smartphone-based instruments. Then, on a periodic basis (e.g., bi-weekly), the user's health status is assess via brief screening questionnaires in five domains (i.e., stress, anxiety, sleep quality, depression, and alcohol use). For each domain, the screening data are analyzed by the iVA and a subsequent detailed assessment is given should the screener score meet certain criteria. Any such detailed assessment is categorized by none, mild, moderate, or likely risk of disease for that domain.

Persons with likely risk are advised to consult their primary care provider for a professional health assessment. Persons with mild or moderate risk (i.e., subclinical scores), are presented with a suite of interventional, therapeutic, and monitoring activities to support post traumatic stress reduction. These include health management information (i.e., cognitive lessons), skills acquisitions (e.g., meditation, muscle relaxation), tools (e.g., sleep hygiene checklist), and self-monitoring activities (e.g., alcohol use diary). All of these screening instruments, assessment instruments, and self-help interventional activities, as well as the iVA health management expert system, are components of the PHIT for Duty smartphone/tablet mobile application. The "to-do" list of assessments and activities to be performed by the user is updated daily and displayed on the PHIT for Duty task list screen.

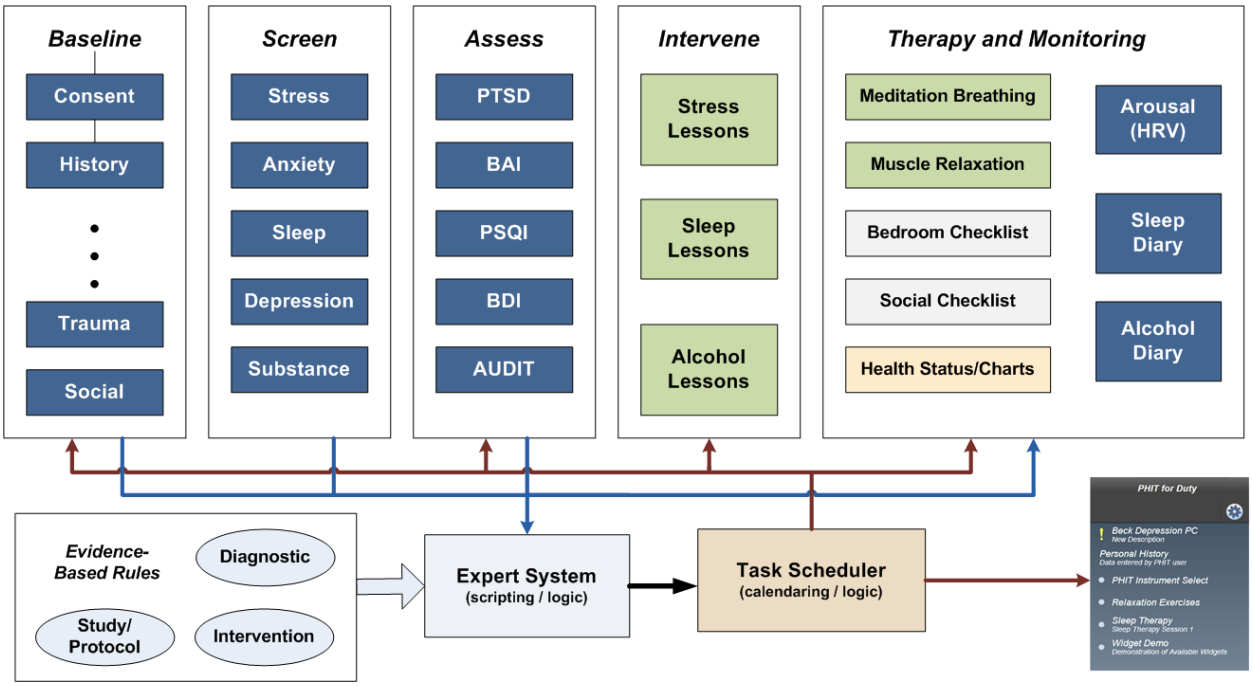


Exhibit 3. PHIT for Duty health assessment and preventive intervention schema.

2.2.2. Psychometric assessment and scheduling

Based on the design inputs set by our internal science team, a suite of psychological, behavioral, social, and other health assessments has been developed and is now in testing. Each assessment instrument (e.g., Beck Anxiety Inventory) was scripted using an XML-based language as specified in the PHIT architectural documentation. The science team has also scripted the iVA logic, which will direct the scheduling of instruments based on a set of logic rules.

These health assessments comprise a range of health domains (**Exhibit 4**), including trauma exposure, PTSD symptoms, anxiety, depression, sleep quality, and substance use. Some measures will be taken only at baseline, such as the Combat Exposure Scale. Others will be taken periodically (e.g., weekly) as screeners, and if instrument-specific thresholds are exceeded, a more detailed assessment will be made via another instrument. The status of these periodic health assessments will be used to recommend stratified self-help interventional activities to be carried out by the user on the smartphone. The decisions about which screeners, instruments, and SHI to present will be made by the iVA. Design and development of software for these interventional activities, such as cognitive therapy for anxiety, has begun and will be completed by June 2012.

Exhibit 4. Self-assessment Instruments Implemented for the PHIT for Duty Study

Baseline instruments

Personal Data	User Demographics and History	n/a
Combat exposure	Combat Exposure Scale (CES)	Keane et al., 1989
Head injury	Concussion Checklist (CCL)	McCrory et al., 2004
Coping	Brief Coping Scale (BCOPE)	Carver, 1997
Resilience	Connor-Davidson Resilience Scale (CDRS)	Connor et al., 2003
Emotional Regulation	Difficulties in Emotion Regulation Scale DERS)	Gratz and Roemer, 2004
Distress	Impact of Event Scale (IES)	Horowitz et al., 1979

Monitoring instruments

Primary measures

PTSD	Short Screening for PTSD (PTSD7)	Breslau et al., 1999
Sleep	Pittsburgh Sleep Quality Index (PSQI)	Buysse et al., 1989
Alcohol	The CAGE Questionnaire (CAGE)	Ewing, 1984
Anxiety	General Anxiety Disorder (GAD7)	Spitzer et al., 2006
Depression	Beck Depression Inventory for Primary Care (BDIPC)	Beck et al., 1996

Secondary measures

Stress	Perceived Stress Scale-4 (PSS4)	Cohen et al., 1983
Social	Multidimensional Scale of Perceived Social Support	Zimet et al., 1988
TBI	The Brief Traumatic Brain Injury Screen (TBI3)	Schwab et al., 2006

Full-scale assessment instruments

Primary measures

PTSD	PTSD Checklist-Military (PCLM)	Weathers et al., 1993
Sleep	Pittsburgh Sleep Quality Index (PSQI)	Buysse et al., 1989
Alcohol	Alcohol Use Disorder Identification Test (AUDIT)	Babor et al., 2001
Anxiety	Beck Anxiety Inventory (BAI)	Beck et al., 1988
Depression	Beck Depression Inventory (BDI)	Beck et al., 1961

Secondary measures

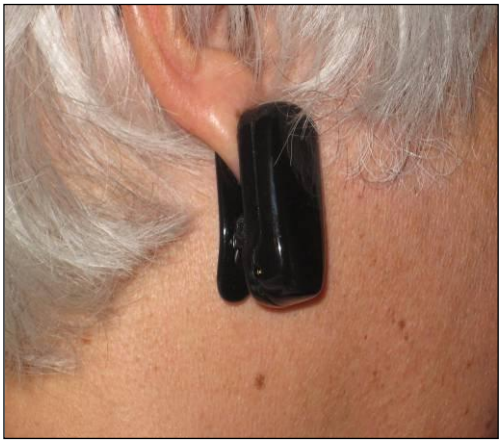
Stress	Stress Questionnaire (STRESSOR)	
Social	Multidimensional Scale of Perceived Social Support	Zimet et al., 1988
TBI	Rivermead Post Concussion Symptoms Questionnaire (RPQ)	King et al., 1995

Supporting instruments

Sleep	Pittsburg Sleep Quality Index Addendum (PSQIA)	Germain et al., 2005
Stress	Perceived Stress Scale-10 (PSS10)	Cohen et al., 1983
Reactivity	Simple Reaction Time	

2.2.3. Psychological arousal

Exhibit 5. Wireless Pulse Sensor



For objective measurement of psychological arousal, we developed a system comprising a wireless pulse sensor clipped to the earlobe (**Exhibit 5**) and software to display ear pulse, heart rate (HR), and heart rate variability The pulse sensor (Binar HeartSensor model HRS-08WE, Binar Integrated Mobile Systems, LLC, Poulsbo, WA) is a very small and unobtrusive device linked to the smartphone via a Bluetooth wireless connection, and therefore can be used to assess cardiac arousal almost anywhere and anytime. We tested the device during a range of activities at rest and during exercise, and have found the ear pulse wave to be free of artifacts and usable up to 4 hours on a battery charge.

Development of software integrating the ear lobe pulse sensor on Android mobile devices is complete. The PHIT BINAR software module receives a continuous pulse waveform sampled at 300 Hz, uses several digital filters to clean the waveform, and provides these data to the PHIT heart rate (HR) analysis module as a real time background process. At a specified interval (e.g., every 5 seconds), the HR analyzer examine the prior 60 seconds of pulse information and determines the average HR, the average interbeat interval (IBI), and measures of HR variability (e.g., RSA). The raw and clean HR waveforms and derived HR and HRV measurements are stored in the PHIT database and plotted on the device (**Exhibit 2**).

2.2.4. Sleep quality

Since sleep problems are frequently associated with hyperarousal and PTSD (Gellis et al., 2010), we proposed to develop some measurement technology for objective assessment of sleep quality, rather than a mere questionnaire (e.g., PSQI), that could be used in near real time with smartphones or other portable devices. Actigraphy, which employs motion sensors attached to the wrist, is an obvious candidate; however the commercially-available systems do not interface with smartphones. Furthermore, actigraphy has been found to be better in assessing sleep/wake cycles rather than sleep quality (Pollak et al., 2001). Consequently we were looking at alternatives.

Exhibit 6. Zeo Headband

A relatively new device that we have begun to evaluate is the Zeo Sleep Manager (Zeo Inc., Newton, MA). This validated device (Shambroom et al., 2012) uses an unobtrusive headband (**Exhibit 6**) to sense sleep patterns and send the data wirelessly to a mobile device, on which the patterns of REM, light, and deep sleep and wakefulness are charted. Software integrating the Zeo sleep monitor software on Android mobile devices is complete.

The Zeo sleep manager mobile sleep monitoring sensor device uses an unobtrusive headband to sense sleep patterns and send the data wirelessly to a mobile device, on which the patterns of REM, light and deep sleep and wakefulness are charted. Zeo provided us with a software-development kit so that we could transfer the acquired sleep data each morning from the Zeo software to the PHIT for Duty database. After receiving the Zeo data, a chart of sleep efficiency is produced and made available for user feedback (**Exhibit 2**).

As another objective measure of sleep quality, we intended to use the W3Tilt Bluetooth 3 axis accelerometer as a measure of body movement based on software previously developed under a concept award. However, the device is no longer on the market. Recently Sony released their SmartWatch which includes a 3-axis accelerometer in a wrist-worn package and wireless Bluetooth communication to Android devices. We therefore began developing software to integrate the Sony SmartWatch accelerometer sensor with the PHIT platform. We have found that we can acquire reliable 3-axis body motion data at 5 Hz using this device and will soon fully integrate it into the PHIT sensor library.

2.3. Task 3: Beta testing in civilians

Two rounds of beta testing have been completed, each with four participants. In both rounds, participants used the PHIT device to enter pre-determined scripted answers to a set of psychological health questionnaire. The first round was a one-week test and the second round was a two-week test. Prior to using the device, each participant was advised about the purposes, risks, and benefits of their participation and asked to provide informed consent. They were then trained on using the devices, and allowed to take the devices home for their use over their designated one or two-week duration. At the end of this period, the devices were returned to RTI and the participants were debriefed (**Exhibit 7**) on general usability, issues with data entry for the psychological questionnaires, any technical problems they might have experiences, the quality and methodology of the training, and suggestions for improvement in any aspect of the technology.

In addition to these beta tests, two rounds of functional testing of the Binar ear pulse monitor, the Zeo sleep monitor, the sleep self-assessment instruments, and the mindfulness-based stress relaxation training were completed on the related ONR project. The first round had four participants and the second round with six participants will be completed on December 21. Usability data have been acquired for the first round only, as the second round is not yet finished. Based on these data and data the ONR-related field tests, we reviewed the usability feedback reports, gather lessons learned from our field staff, and examine any technical issues that had been identified during the field tests. We then decided on relevant issues and made the necessary software revisions. With each experiment we improved quality, added new features, and gathered additional information to help produce a better product.

Exhibit 7. Preliminary results from PHIT usability tests in a civilian population

Usability Question	Mean and Standard Deviation
Would you say the device was: 1-very hard to use; 2-hard to use; 3-neither; 4-easy to use; 5-very easy to use?	4.00 ± 0.53
How hard or easy was it for you to enter your sleep info? 1-very hard; 2-hard; 3-neither; 4-easy; 5-very easy.	4.50 ± 0.53
Did you ever choose not to enter information? (yes=1; no=2)	2.00 ±1 0.0
Did you have any technical problems with the devices or software application? (yes=1; no=2)	1.38 ± 0.52
Do you feel the training you received was adequate? (yes=1; no=2)	1.00 ± 0.00
How likely would you be to do this same study again for the same amount of money? 1-no way; 2-unlikely; 3-not sure; 4-likely; 5-definitely.	5.00 ± 0.0

During early 2013 we suspended field data collection to review existing data and make any necessary revisions to the PHIT software to ensure quality data collection and publishable results from the final round of testing. We expect to complete beta testing by June of 2013. With 20 the additional participants, we believe that we will have sufficient data to publish on the technical performance and usability of the system under field conditions.

2.4. Task 4: Pilot study in service members

A human studies research protocol, including consent form, recruitment processes, and a focus group interview guide, was submitted to the RTI Institutional Review Board (IRB) for review. After several rounds of consideration, the RTI approval was granted on 29 October 2012 and provided to COL Earles at Fort Bragg for submission to the WAMC IRB. Since then CAO Earles has provided the WAMV IRB forms to RTI and we are preparing these form mission in late April 2013. We expect that the pilot study will be conducted during the summer of 2013.

2.5. Randomized controlled trial in post-deployed personnel

No work to date on this task.

2.6. Task 6: Migration to other smartphones and tablets

As mobile devices become more prevalent, so does the range of possibilities for medical applications to gather data using these devices. Since the user community employs a variety of technologies, and development tools vary across platforms, engineers generally select a single platform for development. This approach reduces the number of devices the application can run on, reduces new features, and imposes additional cost while the team re-implements the application for different smartphone and tablet devices.

To avoid these issues, we examined several cross-platform development tools to determine their efficacy and applicability for PHIT development. The result was our selection of Adobe Flash Builder for software development and the Adobe Interactive Runtime (AIR) for execution on multiple mobile platforms (**Exhibit 8**). Applications developed for Adobe AIR will not only execute on devices using the Google Android and the Apple iOS operating systems, but also on Microsoft Windows and Apple desktop computers. (Due to limitations of the platform, we will not support BlackBerry versions.) Of course not all of the application features may be supported on all devices, such as GPS location identification, as such resources are not universally available. However, the PHIT software is designed to tailor itself to those resources that are available, and for which the user has govern permission.

Using Adobe Flash Builder, software is developed in Adobe Actionscript, an advanced object-oriented language that is very similar to Java and Javascript. User screens are designed using MXML, an object-oriented layout language for media-rich interactive graphical interfaces. Packaging for Android or iOS is as easy as selecting the particular export platform when building the project. For Android, the package requires the Adobe AIR runtime to be installed on the mobile device. For iOS, a native iOS binary is generated which includes all necessary runtime support.

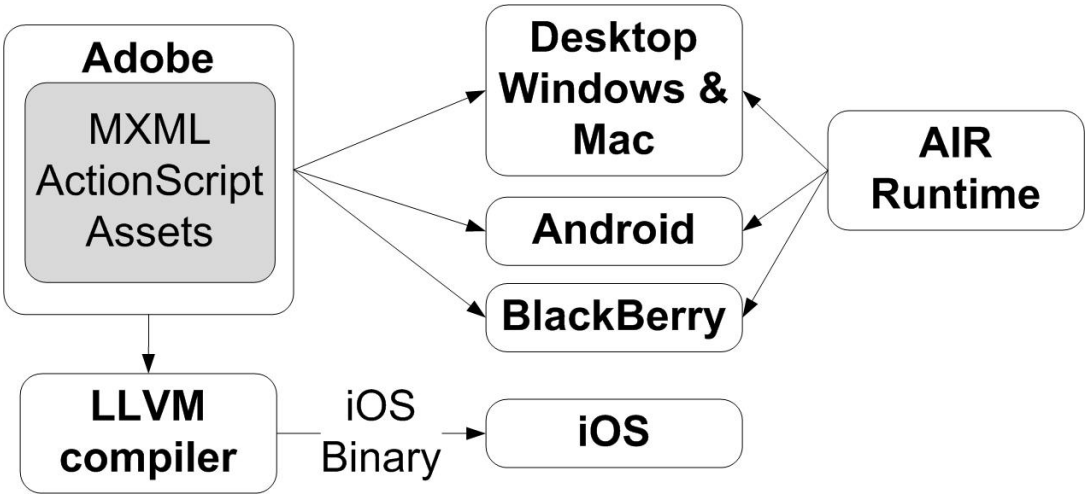


Exhibit 8. Cross-platform development methodology using the Adobe AIR runtime.

3. KEY RESEARCH ACCOMPLISHMENTS

To date the main research accomplishments have been substantial completion of the PHIT for Duty application and initial demonstration of usability in an age-appropriate civilian population. The generic platform upon which PHIT is being built is highly extensible, flexible, and secure. Developing PHIT components such as instruments, activities, and iVA modules is straightforward yet the XML structures provide considerable power in customizing the content. For example, subscores and the overall score for a user for a questionnaire (e.g., for anxiety) is immediately available to the iVA, which is able to determine how to proceed with the user. The iVA may choose to schedule a screening for a future date, to place a SHI on the user's task list, or, if necessary, contact a clinician for referral. Variations of instruments, new instruments that focus group participants suggest are important, and advisory content that improves the PHIT device's usability are all able to be easily accommodated.

Additionally, we have worked with clinical experts to implement a range of domains and instruments that are evidence-based, and thus justifiable. For example, the primary domains are those that clinicians feel are most important to the target population for PHIT, and the iVA's underlying algorithms are written to carefully consider variation in assessments of these domains. Other data (e.g., resilience, combat exposure, and family history) are captured through additional validated and custom instruments that will be used as covariates in analyses to better explain trends found in the main domains.

PHIT for Duty, a mobile health application for reducing the impact of stress exposures in military personnel, provides psychological health assessment and tailored health interventions on a smartphone or tablet platform. With mobile technology, PHIT for Duty provides privacy which may help reduce stigma and encourage user adherence to personal assessment and interventions. Initial evaluations of PHIT instrument interactions, physiological sensors, system functionality, system acceptability, and overall usability have shown positive results and affirmation of the PHIT mobile application framework design.

4. REPORTABLE OUTCOMES

4.1. Manuscripts, abstracts, presentations

During the last project year, the following publications and presentations were made based on projects using either the PHIT framework or the PHIT for Duty mobile application:

Kizakevich, P. N., Eckhoff, R. P., Lyden. J., Hubal, R, and Brown, J.. (2013, February). *PHIT for Duty™, a Mobile Health Assessment and Intervention Application for Post Traumatic Stress and Psychological Disorders*. Poster presented at Digital Health Communication Extravaganza, February 21, 2013, Orlando, FL.

Kizakevich, P. N., Hubal, R. C., Brown, J. M., Lyden, J. T., Spira, J. L., Eckhoff, R. P., Zhang, Y., Bryant, S. P., & Munoz, G. (2012). PHIT for Duty, a Mobile Approach for Psychological Health Intervention . *Studies in Health Technology and Informatics*, *181*, 268–272. doi:10.3233/978-1-61499-121-2-268

Bagwell, J. E., Furberg, R. D., Kizakevich, P. N., Eckhoff, R. P., Zhang, Y., Bakalov, V. D., Simoni, D. A., Hobbs, C. L., & LaBresh, K. A. (2013, April). *A mobile clinical decision support tool for implementing the NHLBI Expert Panel Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents*. Poster presented at mHealth@Duke 2013, Durham, NC.

Zhang, Y., Roe, D. J., Keating, M. D., Kizakevich, P. N., Eckhoff, R. P., Bryant, S. P., Munoz, G., & Hubal, R. C. (2012, May). *SurveyPulse - A Cross-Platform Mobile Survey App Created with Adobe Flex*. Presented at IFDTC, Orlando, FL.

During the previous project years, the following publications and presentations were made based on projects using either the PHIT framework or the PHIT for Duty mobile application:

Kizakevich, P.N. (2012, January). *Mobile technologies for health monitoring and intervention*. Invited presentation, Raleigh Engineers Club, Raleigh, NC.

Eckhoff, R.P., Kizakevich, P.N., Zhang, Y., & Hubal, R.C. (2012, February). *Personal Health Intervention Tool: A mobile framework using Adobe Flash Builder*. Poster presented at the Digital Health Communication Extravaganza, Orlando, FL.

Hubal, R. (2012, April). *The imperative for social competency prediction*. Talk presented at the Social Computing, Behavioral Modeling and Prediction Conference, College Park, MD.

4.2. Licenses applied for and/or issued

- No patents or disclosures have been filed.
- RTI plans to copyright the PHIT platform and PHIT for Duty source code and application.

- The PHIT platform may be recognized as a medical device; currently an investigational device exemption has been granted by RTI's IRB.

4.3. Degrees obtained that are supported by this award

None

4.4. Development of cell lines, tissue or serum repositories

Not applicable

4.5. Infomatics such as databases and animal models

None

4.6. Funding applied for based on work supported by this award

The Office of Naval Research has awarded a contract to RTI International for related work (ONR N00014-11-C-0129). This project, also called PHIT for Duty, a Personal Health Intervention Tool for Psychological Health and Traumatic Brain Injury, will support the overall PHIT research and development program with studies designed to validate aspects of the PHIT methodology, software applications, and hardware platform. Specifically, we will conduct the following two studies to validate methods for assessing psychological health that will be incorporated in the PHIT for Duty system.

Mini-study 1: Evaluate the efficacy of PHIT psychological arousal and sleep quality assessment methodologies. For psychological arousal, the objective is to evaluate heart rate variability monitoring for measurement of arousal and the efficacy of PHIT SHIs for stress relaxation training. These assessments will be conducted by comparing PHIT-derived measures with standard noninvasive methods of assessment, such as changes in skin conductivity. For sleep quality assessment, the objective is to evaluate body motion monitoring via noninvasive accelerometry for body posture and movement assessment during sleep. These assessments will be conducted by comparing PHIT-derived measures with standard noninvasive methods of assessment, such as wrist-motion actigraphy.

Mini-study 2: Evaluate the accuracy of psychological assessment scores. The objective is to evaluate how well the self-conducted psychological health assessments incorporated in the PHIT for Duty platform compare with standardized assessments being conducted by trained clinical professionals.

4.7. Employment or research opportunities applied for and/or received based on experience/training supported by this award

During the last project year, the research opportunities listed below have been applied for based on projects using either the PHIT mobile technology framework or the PHIT for Duty mobile application. Furthermore three additional proposals are in preparation for submission by June 2013 for mobile health studies in military and civilian populations that will employ PHIT mobile health technologies.

- **Risk Factors in Obese Students Using mHealth Technologies at HBCUs**
  NIH proposal submitted by Winston-Salem State University in collaboration with RTI International

- **Mobile Health Application for Family and Behavioral Health Provider**
  DoD STTR Phase 1 proposal submitted by SoarTech in collaboration with RTI International

- **Active Authentication Phase II**
  DARPA proposal submitted by RTI International

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